



Material Control and Accountability (MC&A)

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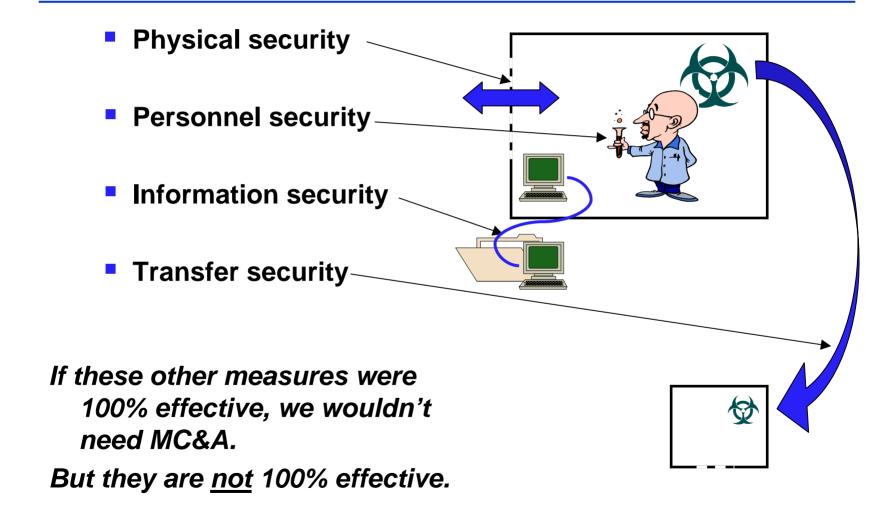
Outline

- Overview
 - Context
 - Objective
 - Not Accountancy
- Material
- Control
- Accountability
- Benefits & Challenges
- Summary





Material Control and Accountability complements other aspects of biosecurity.







The objective of material control and accountability is...

...to assure the complete and timely knowledge of

- What materials exist
- Where the materials are
- Who has access to them





Material control and accountability should not be...

- A needless way to make valuable research difficult
- Nuclear safeguards applied mindlessly to biological materials
- Material balance accountancy

The "A" in biosecurity MC&A

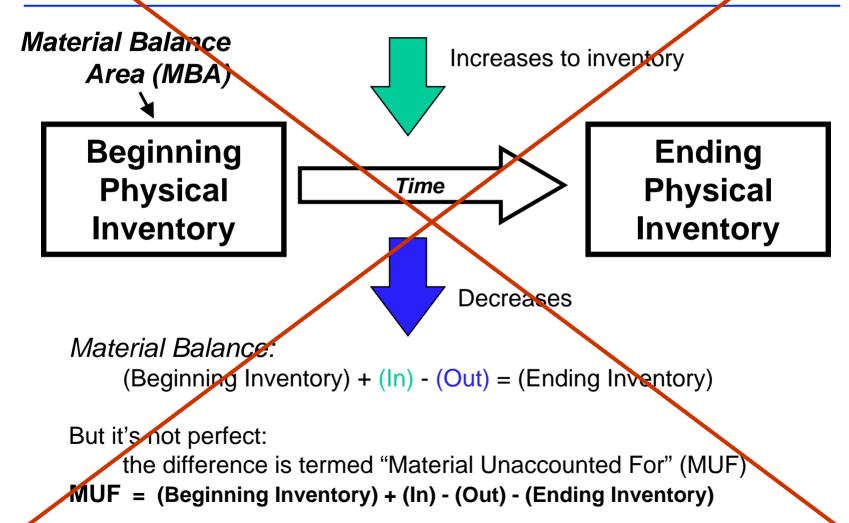
does not mean

"Accountancy"





Accountancy seeks to verify the "material balance" for a "material balance area."







The principal issues for material control and accountability involve defining precisely:

- What materials are subject to MC&A measures
- The operating procedures associated with the materials
 - where they can be stored and used
 - how they are identified
 - how inventory is maintained
- What records need to be kept for those materials and the timeliness requirements for those records
- What accountability means
- Documentation and reporting requirements

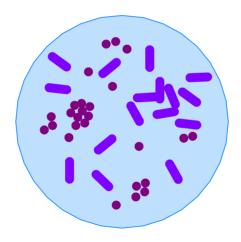




Material Control and Accountability

What do we mean by "material"?

High Consequence Pathogens and Toxins (HCPTs)



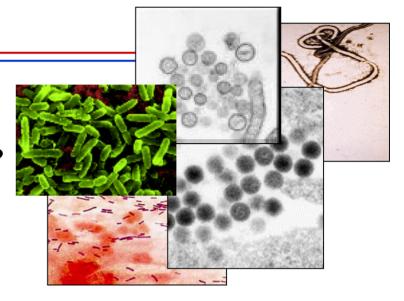
 MC&A deals directly with the primary asset we are trying to protect: the biological organisms.





Defining "material" is complicated.

- Agent
 - What do we consider HCPTs?
 - Viable? Whole organism or DNA?
- Quantity
 - Any amount can be significant
 - A threshold amount for toxins
- Form
 - Repository stocks, working samples, in host, contamination
- Detail—what level is adequate for MC&A?
 - Material as items
 - Each vial as a separate inventory record?
- Capture—when does MC&A start & stop?
 - Naturally occurring; clinical samples; disposition
- Other Issues?
 - Uniformity: government/ commercial/ academic/ other owner
 - Future: genetic engineering, chimeras, synthetic bugs





Information about "material" is needed for control and accountability.

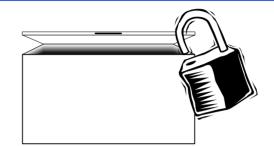
- Attributes: to characterize the material ("what")
 - Agent / strain
 - Origin
 - Date
- Description: to identify a particular item of the material ("which")
 - Container
 - Identification
 - Location
- Type or classification: to assign biosecurity significance ("why")
 - Group

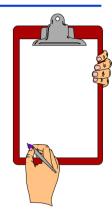




Material Control and Accountability

- Control is either...
 - Engineered / Physical
 - Administrative





- Containment is part of material control
 - Containment Lab / Freezer / Ampoule
- Procedures are essential for material control
 - For all normal conditions:
 - Storage
 - Use
 - Changes: creation, modification, destruction
 - Must also deal with abnormal conditions:
 - Inventory discrepancies, anomalies, accidents





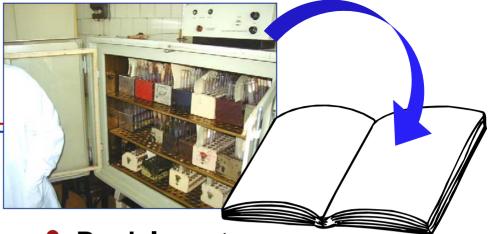
Material Control and Accountability

- All material should have an associated "accountable person"
 - The person best in a position to answer questions about the associated material
 - Not someone to blame!
 - Ensure that no material is "orphaned"
- Procedures ensure accountability
 - Experimental work: laboratory procedures
 - Inventory: know what you have
 - Reporting: document routine MC&A practices
 - Audit/ assessment: is this working?
 - Ensures effective implementation of MC&A
 - Training: personnel understand requirements





- Physical Inventory
 - The actual state of the material inventory
 - Based upon an inventory taking
 - Performed periodically



Book Inventory

- What we think is the material inventory
- Based upon our information record
- Maintained continuously
- Need to compare the book inventory with the physical inventory and reconcile any discrepancies
- Book inventory now an issue for information security:
 - Who needs to know? Who needs to know what?



MC&A:

- Prevents, or makes more difficult, some easy material diversion scenarios
- Documents lab status before any problems occur
 - Better than forensic work afterwards
- Is consistent with and reinforces good laboratory practice

Much of MC&A is likely already done for reasons other than biosecurity...

- Biosafety
- Good research practice
- Business interest





We want to avoid...

- Implementing poor MC&A measures
 - Those that are ineffective and unnecessary
- Making "real work" more burdensome
- Imposing unacceptable costs
 - Time
 - Money
 - Effort
- Spreading knowledge of inventory information





Questions that material control and accountability must satisfy:

- Does it accomplish its intended purpose (improved biosecurity)?
- Is it free of serious unintended consequences?
- Are the tradeoffs worthwhile, or are they too difficult?

The success of MC&A ...

... depends on what we do, and how we do it:

Implementation!



Summary

- MC&A is an important component of biosecurity
 - Complements other measures
 - Applies to the materials of concern
 - Containment
 - Procedures
 - Accountability
 - MC&A for biosecurity is <u>not</u> the same as MC&A for nuclear materials
- MC&A can improve biosecurity, but presents challenges
 - Effective implementation is key

